

REMARKS

The Office Action dated June 29, 2005 has been carefully reviewed. Claims 49-52, 55-61, and 124 are pending in this application. Applicants request reconsideration of this application in light of the remarks presented herein.

CLAIM REJECTIONS BASED ON §102 McKELLOP '220

Claims 49-52, 55-61, and 124 were rejected under 35 U.S.C. §102 as being anticipated by U.S. Patent No. 6,165,220 issued to McKellop et al. (hereinafter "McKellop '220"). Applicants respectfully traverse this rejection.

In the 6/29/05 Office Action, the Examiner argues that the "McKellop et al. bearing has the same structure as Applicants' claimed invention since it has a crosslinked layer and a non-crosslinked layer. Applicants' arguments regarding gel content, chemical composition, wear rate, etc. are not directed to claimed features." It appears that the Examiner believes that structural differences only appear at a "mechanical" or "macro" level (e.g., "since it has a crosslinked layer and a non-crosslinked layer"). Applicants argue that structural differences may also be shown at a chemical or polymer level. Hence, Applicants provided the Examiner with exhaustive literature data which conclusively establishes that structural differences exist between UHMWPE crosslinked by various techniques. These are not "unclaimed features" as purported by the Examiner, but rather are the conventional analytical techniques employed for determining the structural characteristics of polymers such as UHMWPE. These conclusively show that structural differences exist between radiation crosslinked polyethylene and chemically crosslinked polyethylene.

To further advance prosecution of the present application, Applicants have amended independent claims 1 and 56 to recite a "laminar composite bearing" having layers which are molded at "a melt-fused interface". Such a structure is not found in the irradiated bearings of McKellop '220. Note also that claims 1 and 56 have been amended to recite

"radiation crosslinked" polyethylene (as opposed to the previously recited "gamma irradiated polyethylene"). As such, amended claims 1 and 56 are intended to cover, amongst others, both gamma irradiated polyethylene and ebeam irradiated polyethylene.

The invention of independent claims 1 and 56 also defines over the chemically crosslinked bearings of McKellop '220 in which a UHMWPE powder and peroxide are compression molded to either a cold pressed or consolidated base of conventional (non-crosslinked) UHMWPE. In particular, as pointed out in detail in the previously filed response to the 11/4/2004 Office Action, numerous structural differences exist between chemically crosslinked polyethylene and radiation crosslinked polyethylene. The discussion from the previously filed response is reproduced as follows:

Chemical crosslinking of polyethylene starts with heat activation of organic peroxide. Free radicals so generated abstract hydrogen atoms from methylene segments in the polymer chain, thereby creating carbon-based free radicals. The combination of two carbon-based free radicals produces a crosslink in the polyethylene.

Martinotto et al (Reference (3)) reported that crosslinking byproducts can affect, in a negative way, the aging of XLPE cable insulation under thermo-electrical stress. Removal of the byproducts is not always feasible. The byproducts of peroxide crosslinking process are various organic species depending on the starting organic peroxide. For example, Luperox 130 (2,5-dimethyl-2,5-di-(tert-butylperoxy)-3-hexyne), generates tert-butyl alcohol and 2,5-dimethyl-2,5-hydroxyl-3-hexyne residues after its decomposition and extraction of hydrogen atoms from polyethylene. Some of these byproducts are volatile and may diffuse out of polymer. Nevertheless, a majority of the byproducts in peroxide-crosslinked UHMWPE are trapped in the polymer matrix due to limited diffusivity in highly viscous molten UHMWPE mass.

Another aspect of peroxide-crosslinked UHMWPE is the residual peroxide left after curing/molding. The non-reacted peroxide has potential to decompose/degrade as time passes and consequently induces oxidative degradation in polymer. For example, the half life of Luperox 130 is 9 minutes 21 seconds at 170° C, and the minimum curing time at 170° C is as long as 1 hour 33 minutes (the minimum curing time from half life calculator was provided by the specialchem4polymers.com website). It is not uncommon to observe temperature gradient in a mold during molding/curing. Peroxide-crosslinked UHMWPE often requires prolonged annealing to reduce, and possibly eliminate, the last traces of un-reacted peroxide (see, e.g., Reference (2)). Chemically crosslinked UHMWPE, if not thoroughly annealed, may have unexpected degradation tendency.

As such, even though polyethylene crosslinked by the use of different methods can be characterized by a number of structural similarities (e.g., crystallinity), the above-description demonstrates that a structural difference relating to chemical composition does in fact exist between peroxide-crosslinked UHMWPE and gamma-crosslinked UHMWPE. Such a different

chemical composition is characterized by, amongst other things, the presence of decomposition byproducts and potentially un-reacted peroxide residues.

Further evidence of the structural differences is found in the following reference which is being submitted in an IDS concurrently herewith: M. Narkis et al., Structure and Tensile Behavior of Irradiation- and Peroxide- Crosslinked Polyethylenes, Journal of Macromol. Sci. B., pp. 37-58 (1987). (hereinafter "Narkis"). As summarized in the CONCLUSIONS section of Narkis on page 56, structural differences do indeed exist between radiation crosslinked polyethylene and chemically crosslinked polyethylene.

If the Examiner maintains the §102 rejection over McKellop '220, the Applicants respectfully request that the Examiner specifically point out (e.g., column and line number) where McKellop '220 teaches each element of independent claims 1 and 56. Respectfully, the Examiner has not even met his initial burden of developing a proper §102 rejection by merely stating that "McKellop et al. bearing has the same structure as Applicants' claimed invention since it has a crosslinked layer and a non-crosslinked layer" since Applicants' claims do not merely recite a "crosslinked layer" but rather a "radiation crosslinked layer" (or formerly, a "gamma irradiated crosslinked layer"). As a result, the Examiner has not properly shifted the burden to the Applicants to show structural difference. However, despite this fact, Applicants have now on two occasions done so in an effort to advance prosecution of this application. Applicants have populated the prosecution file with numerous trade journal articles and other references which substantiate Applicants arguments. The Examiner has responded with nothing to contradict this evidence. As a result, the record clearly reflects the presence of structural differences between radiation crosslinked polyethylene and chemically crosslinked polyethylene.

As such, the §102 rejection of independent claims 1 and 56 was improper from the beginning, but in any case has now been traversed, and should be withdrawn. The §102 rejection of the remaining claims should also be withdrawn since they are dependent on either claim 1 or 56.

CLAIM REJECTIONS BASED ON §103 - McKELLOP '220 AND SCOTT

Claims 49-52, 55-61, and 124 were rejected under 35 U.S.C. §103(a) as being obvious over McKellop '220 in view of U.S. Patent No. 6,547,828 issued to Scott et al. (hereinafter "Scott"). Applicants respectfully traverse this rejection.

The proposed combination does not arrive at the invention of Applicants' amended claims. As discussed above, to further advance prosecution of the present application, Applicants have amended independent claims 1 and 56 to recite a "laminar composite bearing" having layers which are molded at "a melt-fused interface". Such a structure is not found in the irradiated bearings of McKellop '220, nor is such a structure taught in Scott.

Of course, if the peroxide is removed from the chemically crosslinked bearings of McKellop '220 (as proposed by the Examiner to allow for the substitution of the gamma irradiation technique of Scott), there is likewise no laminar composite since, in the absence of peroxide, the molded bearing consists solely of UHMWPE.

As an aside, in the formation of his rejection, the Examiner appears to be confusing dosage with penetration. Dosage is the product of the energy level of the irradiation source and the exposure time. The energy level of the source is what determines penetration level. Gamma radiation is a deep penetrating energy source. It easily penetrates the entire thickness of UHMWPE acetabular cups (such as the McKellop '220 cups). A typical commercial E-beam source is in the 10 MeV range. At this energy level, penetration occurs at 40-50 mm, which is greater than the typical thickness of an UHMWPE acetabular cup. See McKellop '220 at column 1, lines 56-65 where it is indicated that both gamma and high penetration ebeam (i.e., 10 MeV) crosslinks specimens throughout their entire thickness. See McKellop '220 also at column 6, lines 3046 where it is discussed that 10 MeV e-beam, which is the commercial standard, penetrates deeply into UHMWPE (i.e., 40-50 mm). These passages clearly teach away from the use of gamma irradiation to form the bearings of McKellop '220.

As a result, the Examiner has not established a prima facie case of obviousness with regard to the combination of McKellop '220 and Scott.

CLAIM REJECTIONS BASED ON §103 DEVANATHAN AND LI

Claims 49-52, 55-61, and 124 were also rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,645,594 issued to Devanathan et al. (hereinafter "Devanathan") in view of U.S. Patent No. 6,794,423 issued to Li (hereinafter "Li"). Applicants respectfully traverse this rejection.

Devanathan teaches an acetabular cup formed to include a number of layers (or zones). The first zone has an articulating surface formed therein, and a second zone extending away from the first zone to the bone engaging surface. The first zone consists of UHMWPE, with the second zone consisting of UHMWPE and PMMA dry blended before molding. A third zone (extending toward the bone engaging surface from the second zone) consists essentially of PMMA. See Devanathan, column 1, lines 35-49.

Li teaches a method of crosslinking a prosthetic bearing in which a directly molded bearing (as opposed to extruded or sheet molded) is radiation crosslinked in its final form. Both gamma and electron beam irradiation is used at doses "higher than 4 Mrads, preferably higher than 5 Mrads, and most preferably less than 10 Mrads."

In an apparent attempt to establish a case of obviousness in the present case, the Examiner stated that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to have irradiated the '594 implant [i.e., the Devanathan implant] with gamma radiation, as taught by Li, to improve its wear characteristics." While this statement may be technically accurate (i.e., it is true that gamma irradiation may be used to crosslink the molded acetabular cup of Devanathan), the resultant acetabular cup would not arrive at the invention of Applicants claims. Indeed, to irradiate the Devanathan cup in the manner described by Li would

crosslink the cup throughout its entire thickness. Applicants' claims are directed to a composite having a crosslinked layer and a non-crosslinked layer (or a layer crosslinked to a lesser degree).

On page 4 of the 6/29/05 Office Action, the Examiner argues that "it is well known that the degree of crosslinking of a material is a function of the dosage it receives (see col. 1, lines 49-67 and col. 2, lines 1-3 of Krebs et al. (US 6,365,089)). Thus, if one so desires, the gamma radiation dose could be adjusted to achieve the same degree of crosslinking as e-beam radiation in the McKellop et al. implant." The Examiner appears to be confusing dosage with penetration. Dosage is the product of the energy level of the irradiation source and the exposure time. The energy level of the source is what determines penetration level. Gamma radiation is a deep penetrating energy source. It easily penetrates the entire thickness of UHMWPE acetabular cups (such as Devanathan cups). A typical commercial E-beam source is in the 10 MeV range. At this energy level, penetration occurs at 4.0-5.5 cm, which is greater than the typical thickness of an UHMWPE acetabular cup. See Krebs at column 2, lines 31-54 for a discussion relating to penetration depths. McKellop '220 also supports this notion at column 1, lines 56-65 where it is indicated that both gamma and high penetration ebeam (i.e., 10 MeV) crosslinks specimens throughout their entire thickness. See McKellop '220 also at column 6, lines 3046 where it is discussed that 10 MeV e-beam, which is the commercial standard, penetrates deeply into UHMWPE (i.e., 40-50 mm).

Li is devoid of any discussion relating to the altering of a common, commercially available ebeam source. This makes sense since Li is also devoid of any discussion relating to the desirability of forming a gradient or any other varying degree of crosslinking within the bearing. Li's ebeam techniques appear to crosslink the entire bearing thickness. Applicants argue that at any exposure time, the gamma radiation used by Li will penetrate the entire thickness of its bearings. As such, the irradiation techniques taught by Li would penetrate the entire thickness of Devanathan's acetabular cup. This would crosslink the cup throughout its

entire thickness. As a result, the proposed combination would not arrive at the invention of Applicants claims.

Not only does the combination of Devanathan and Li not arrive at the invention of Applicants' claims, there is no legally sufficient teaching, motivation, or suggestion to combine the two references in the first place. In an attempt to identify such a teaching, motivation, or suggestion the Examiner indicated that one skilled in the art would do so merely "to improve the wear characteristics" of Devanathan's acetabular cup. This is insufficient for a number of reasons. Firstly, for a teaching, motivation, or suggestion to be proper, it must come from the prior art. In this case, crosslinking UHMWPE has been known since the mid-70's, some twenty years before the filing of Devanathan. Yet, Devanathan is silent as to the use of irradiation to crosslink his acetabular cups. The Examiner has not identified where the prior art teaches the purported teaching, motivation, or suggestion that supports the need to modify Devanathan with the teachings of Li. Indeed, the mere fact that Li teaches "gamma irradiation of a UHMWPE implant to improve it wear properties" is not, ipso facto, motivation to combine the teachings with Li with all teachings of UHMWPE implants, let alone the implants of Devanathan. In fact, Li acknowledges that there are tradeoffs to crosslinking. See, e.g., Li, column 2, lines 38-56. In other words, the simple fact that Li teaches "gamma irradiation of a UHMWPE implant to improve it wear properties" does not provide the motivation to combine Li with Devanathan.

Furthermore, not only has the Examiner not offered a legally sufficient teaching, motivation, or suggestion to combine Devanathan and Li, it is believed that no such motivation exists. This is true since Devanathan actually teaches away from the proposed combination with Li. Indeed, the very art on which the Examiner relies teaches the commonly known need to anneal UHMWPE to remove free radicals therefrom subsequent to irradiation crosslinking. See, e.g., Li at column 2, lines 57-65; Krebs column 2, lines 20-30; and Scott column 4, line 66 through column 5, line 4. As described above, Devanathan's acetabular cup consists of significant amounts of PMMA. No one skilled in the art would be motivated to radiation

crosslink the finished acetabular cup of Devanathan, as proposed by the Examiner, since to do so would require post-irradiation annealing at a temperature which closely coincides with the melting temperature of PMMA. Unlike UHMWPE which remains workable above its melting temperature, PMMA turns to a liquid (with the approximate viscosity of honey) above its melting temperature. As such, post-irradiation quenching would completely distort, and effectively destroy, Devanathan's acetabular cup. Legally sufficient motivation cannot be found in such a circumstance.

As a result, the Examiner has not established a prima facie case of obviousness with regard to Devanathan and Li.

REQUEST OF THE EXAMINER

Throughout the current prosecution, the Examiner has attempted to combine or modify references in a manner which purportedly allows radiation to be applied to the bearing in a manner which causes the outer surface of the bearing to be highly crosslinked, yet the remainder of the bearing to be non-crosslinked. For example, the Examiner has purported that gamma irradiation can be readily substituted for the ebeam taught in McKellop '220 because such a substitution is purportedly "well known". At best, the references identified by the Examiner to support such a notion teach the general principle that both gamma and ebeam can be used to crosslink UHMWPE, and that the degree of crosslinking can be altered based on the dose absorbed by the sample. However, as indicated above, it appears that the Examiner is confusing dosage with penetration. To wit, what the Examiner has never done is point to a reference that shows, for example, that gamma irradiation could be used to create a highly crosslinked outer surface, while only penetrating partially (e.g., 2-3mm) into the bearing to create a gradient, as in McKellop '220. If the Examiner believes that gamma radiation can, in fact, be used in such a manner "by merely altering the dosage in a well known manner", it is respectfully requested that the Examiner produce a reference which supports such a "well known" technique. Until such

time, Applicants respectfully traverse any Official Notice or notion that such an application of gamma irradiation is "well known". Along the same line, Applicants also respectfully assert that in the absence of a specific teaching, such as McKellop '220 (where the ebeam energy levels used are less than 1/10th of conventional levels), a reference cannot be properly construed to teach the use of ebeam radiation which only partially penetrates an orthopaedic bearing.

Having said all of this, if the Examiner maintains any of the current rejections, or creates new ones, in which the Examiner is relying on the application of radiation to penetrate only partially through a UHMWPE specimen to create a composite, it is respectfully requested that the Examiner specifically indicate (e.g., by column number and line number) where the applied prior art reference teaches controlling the penetration depth of the radiation in such a way.

CONCLUSION

In view of the foregoing amendments and remarks, it is submitted that this application is in a condition for allowance. Action to that end is hereby solicited.

It is respectfully requested that, if necessary to effect a timely response, this paper be considered as a Petition for an Extension of Time sufficient to effect a timely response and shortages in other fees be charged, or any overpayment in fees be credited, to the Account of Barnes & Thornburg, Deposit Account No. 10-0435 with reference to file 265280-68002.

Respectfully submitted,
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